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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,687	11/21/2005	Sam A. Deadwyler	C21-074US	4031
	7590 03/18/2009 JDOL SAPONE, P.C.		EXAMINER	
714 COLORADO AVENUE			KIM, JENNIFER M	
BRIDGE POR	Г, СТ 06605-1601		ART UNIT	PAPER NUMBER
			1617	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/541,687 DEADWYLER ET AL. Office Action Summary

Office Action Gammary	Examiner	Art Unit					
	JENNIFER MYONG M. KIM	1617					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address							
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONITHS from the mailing date of the communication.  If NO period for reply is specified above, the mancium statutory period we have a support of the provision of	TE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be tin ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this o D (35 U.S.C. § 133).	•				
Status							
1) Responsive to communication(s) filed on 05 Ju	ly 2005.						
2a) This action is FINAL. 2b) This	action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4) Claim(s) 1.2.4-33 and 35 is/are pending in the	• •						
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6) Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.							
8)⊠ Claim(s) <u>1.2.4-33 and 35</u> are subject to restricti	on and/or election requirement.						
Application Papers							
9)☐ The specification is objected to by the Examiner.							
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of:							
1.☐ Certified copies of the priority documents have been received.							
Certified copies of the priority documents have been received.      Certified copies of the priority documents have been received in Application No							
Copies of the certified copies of the priority documents have been received in Application No      Copies of the certified copies of the priority documents have been received in this National Stage.							
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
oce the attached detailed office action for a list of the certified copies not received.							
Attachment(s)							
1) Notice of References Cited (PTO-892)	Interview Summary     Paper No(s)/Mail Da	(PTO-413)					
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Imformation Disclosure Statement(s) (PTC/95/08)	5) Notice of Informal P						
Paper No(s)/Mail Date	6) Other:						

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# DETAILED ACTION

#### Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 21-23, drawn to a composition comprising an AMPA receptor potentiator having a compound of structure set forth in claim 21, classified in class 514, subclass 385.
- II. Claims 24, and 25, drawn to a composition comprising an AMPA receptor potentiator having a compound structure set forth in claim 24, classified in class 514, subclass 449.
- III. Claims 26-32, drawn to a composition comprising an AMPA receptor potentiator having a compound structure set forth in claim 24, classified in class 514, subclass 309.
- IV. Claims 33 and 35, drawn to a composition comprising an AMPA receptor potentiator including CX516, classified in class 514, subclass 315.
- V. Claims 2 and 3, drawn to a method for treating or preventing cognitive impairment comprising adminsitering an AMPA receptor potentiator having a compound of structure set forth in claim 2, classified in class 514, subclass 385.
- VI. Claims 4 and 5, drawn to a method for treating or preventing cognitive impairment comprising adminisitering an AMPA receptor potentiator having

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a compound of structure set forth in claim 4, classified in class 514, subclass 449.

- VII. Claims 6-12, drawn to a method for treating or preventing cognitive impairment comprising adminsitering an AMPA receptor potentiator having a compound of structure set forth in claim 6, classified in class 514, subclass 309.
- VIII. Claims 13 and 23, drawn to a method for treating or preventing cognitive impairment comprising adminsitering an AMPA receptor potentiator such as CX516, classified in class 514, subclass 315.
- \*\*Claims 1 and 14-19 are generic for Groups V-VIII, therefore, they will be examined with an elected group from V-VIII.
- \*\*Claim 20 is generic for Groups I-IV, therefore, it will be examined with an elected group from I-IV.

The inventions are distinct, each from the other because of the following reasons:

Inventions Groups I-IV and Groups V-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product since the product can be used to treat Attention Deficit Hyperactivity Disorder (ADHD).

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Inventions Groups I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation since each of the compounds to be utilized have different structural moiety having unrelated chemical/physical properties.

Inventions Groups V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of effects since each of the compounds to be utilized have different structural moiety having unrelated biological pathways involving different mechanisms.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification:
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

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(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries):

- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

## Election of species

If Applicants' elect a single Group from Groups I-VIII above, following election of species is required:

This application contains claims directed to the following patentably distinct species various AMPA receptor potentiator. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single ultimate disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, an AMPA receptor potentiator is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of

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search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the

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prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

# Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

# Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/ Primary Examiner, Art Unit 1617

Jmk March 16, 2009